A PROSPECTIVE STUDY OF

FUNCTIONAL OUTCOME OF DISPLACED MIDSHAFT CLAVICLE FRACTURES TREATED WITH INTRAMEDULLARY TITANIUM ELASTIC NAIL SYSTEM

Dissertation submitted to

THE TAMILNADU DR.MGR MEDICAL UNIVERSITY

CHENNAI- 600032

in partial fulfilment of the regulations

for the award of the degree of

M.S (ORTHOPAEDIC SURGERY)

BRANCH II

GOVT. KILPAUK MEDICAL COLLEGE

CHENNAI- 600 010

APRIL- 2016

CERTIFICATE

This is to certify that this dissertation entitled '***A PROSPECTIVE STUDY OF*** **FUNCTIONAL OUTCOME OF *DISPLACED* MIDSHAFT CLAVICLE FRACTURES TREATED WITH INTRAMEDULLARY TITANIUM ELASTIC NAIL SYSTEM'** is a record of bonafide research work done by **Dr. SASI KUMAR. S**, post graduate student under my guidance and supervision in fulfilment of regulations of The Tamilnadu Dr. M.G.R. Medical University for the award of M.S. Degree Branch II (Orthopaedic Surgery) during the academic period from 2013 to 2016, in the Department of Orthopaedics, Govt. Kilpauk Medical College, kilpauk, Chennai-600010

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DECLARATION

I **Dr. SASI KUMAR S,** solemnly declare that the dissertation, '***A PROSPECTIVE STUDY OF*** **FUNCTIONAL OUTCOME OF DISPLACED MIDSHAFT CLAVICLE FRACTURES TREATED WITH INTRAMEDULLARY TITANIUM ELASTIC NAIL SYSTEM'** is a bonafide work done by me in the Department of Orthopaedics, Govt. Kilpauk Medical College, Chennai under the guidance of Prof. K. Raju, M.S.Ortho., D.Ortho., Professor of Orthopaedic Surgery, Govt. Kilpauk Medical College, Chennai-600010.

This dissertation is submitted to "THE TAMILNADU DR. M.G.R MEDICAL UNIVERSITY", towards partial fulfilment of regulations for the award of M.S.DEGREE BRANCH II (Orthopaedic Surgery).

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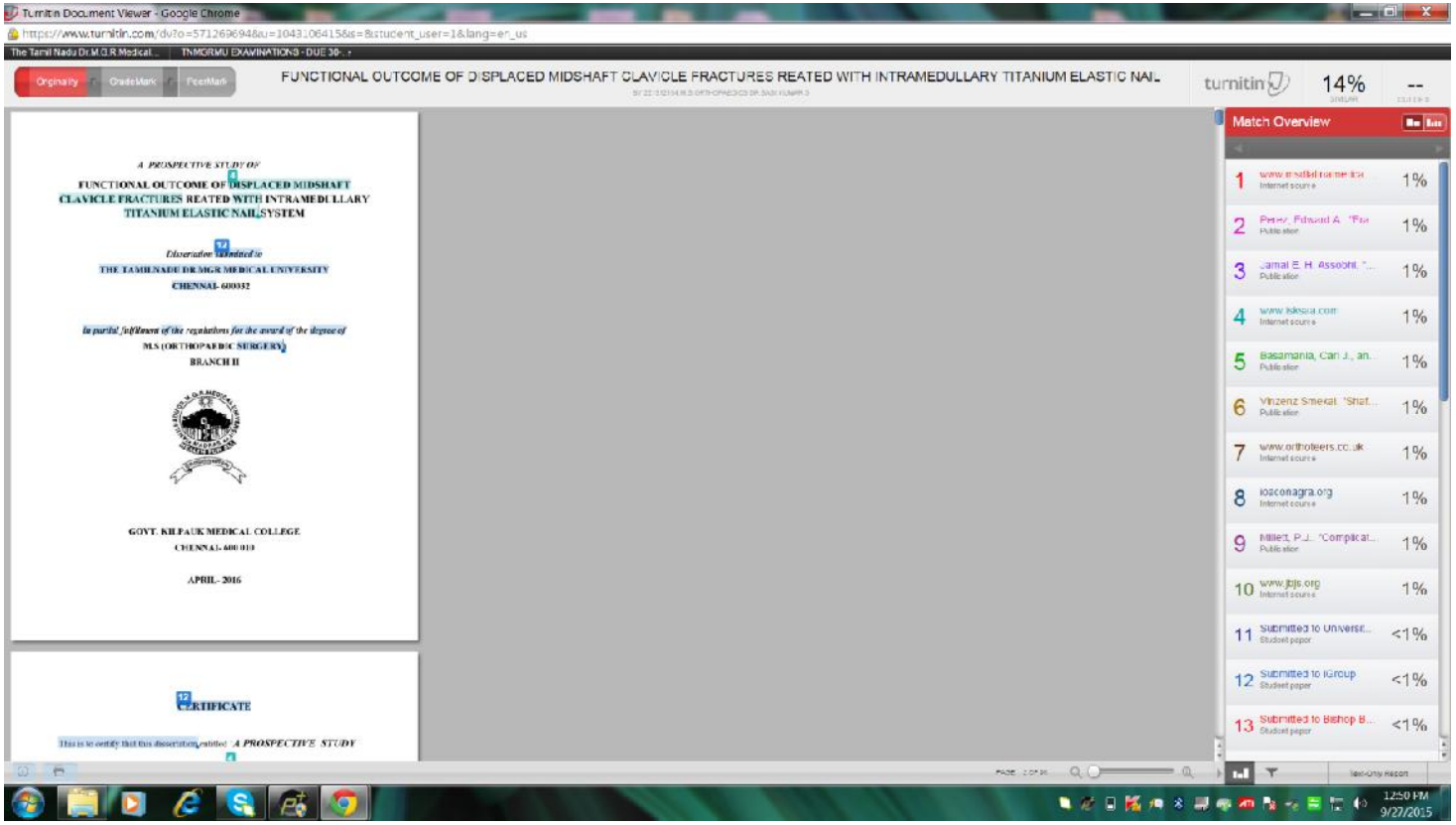
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CERTIFICATE OF APPROVAL

The Institutional Ethical Committee of Govt. Kilpauk Medical College, Chennai reviewed and discussed the application for approval "A Study of functional outcome of displaced midshaft clavicle fractures treated with intramedullary titanium elastic nail system".- For Project Work submitted by Dr.S.Sasikumar, Post Graduate in MS (Ortho), Govt. Kilpauk Medical College, Chennai.

The Proposal is APPROVED.

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.

27/3/15

CHAIRMAN,
Ethical Committee
Govt. Kilpauk Medical College, Chennai

27/3/15

INTRODUCTION

Clavicle fractures are common injuries in young and active individuals, especially those who participate in sports where high-speed falls (e.g., bicycling, motorcycles) or violent collisions (e.g. Football, hockey) are frequent, whereas in children and elderly they are related to falls and they account for approximately 2.6% of all fractures. (27,28,34).

The most common site of fracture in the clavicle occurs at the middle third and which accounts for almost 80% of all clavicle fractures.

Older studies suggested that a fracture of the shaft of the clavicle, even when significantly displaced, was an essentially benign injury with an inherently good prognosis when treated non operatively. (3, 36).

Neer reported a non-union rate of 0.1% with conservative treatment (3) and Rowe corroborated these findings in 1968 and showed a non-union rate of 0.8% in conservatively managed patients. (4) Since then, however, other authors have failed to demonstrate similar good results with conservative treatment. (5, 6) This may be due to the fact that the initial series included children and adolescents and their enormous potential for bone healing may have skewed the results, and

that patient-based scoring systems were not used in the initial series to record the outcome.

In a meta analysis of the literature from 1975 to 2005, Zlowodzki et al found that the non-union rate for non operatively treated displaced midshaft clavicle fractures was 15.1%, higher than what was described previously. (11)

Treating conservatively, Hill et al reported a non union rate of 15% in correlation with initial shortening greater than 2 cms. 31% of patients who were reviewed in the study of Hill et al were not satisfied with treatment results. (7)

Thus, displaced midshaft clavicle fractures can cause significant, persistent disability, even if they heal uneventfully. Thus, there is a trend towards surgical fixation of clavicle fractures based on the unsatisfactory data obtained from conservative treatment.

Good results with high union rates and low complication rates have been reported from a variety of techniques for primary fixation of displaced fractures of clavicle. The clavicle which is similar to other long bones are usually best treated with intra medullary methods.

So elastic stable intra medullary nailing (ESIN) is recommended for all simple displaced midshaft clavicle fractures in order to minimize the rate of delayed union, non union, symptomatic malunion and other complications.

AIM OF THE STUDY

To analyze the functional outcome of displaced midshaft clavicle fractures treated by intramedullary titanium elastic nail system.

REVIEW OF LITERATURE

Hill et al. did a study on 52 cases of conservatively treated adults with mid-shaft clavicle fractures at a mean of 38 months after injury. Unsatisfactory results were reported by sixteen patients (31%) following non operative treatment.

The fracture shortening of 20 mm at initial stage showed high significant association with nonunion and thus increasing the chance of an unsatisfactory result. Shortening of 20 mm or more finally following fixation was associated with an unsatisfactory result, but not with nonunion. No other patient variable, fracture characteristic or treatment factor had a significant effect on final outcome(5).

Surgery has been indicated for completely displaced fractures, potential skin perforation, shortening of clavicle by more than 20 mm, neurovascular injury, and floating injury.(8) The gold standard for the surgical treatment has been open reduction and plate fixation through a large incision.(8)

Other surgical options include intramedullary pinning with Kirschner wire, Rush pins, Knolwes pin, Steinman pin, Haige pin, titanium elastic nail system, and external fixation. Among the

intramedullary devices, titanium elastic nail has been found to be most acceptable tool for fixing clavicle fracture.

Intramedullary fixation for clavicle fractures was first described by peronei in 1950 (10).A systematic review showed relative risk reduction of 72% and 57% for non-union when using intramedullary fixation and plate fixation, respectively, when compared with non-operative treatment of midshaft clavicle fractures.(11)

Intramedullary devices act as internal splints which maintains alignment without rigid fixation.

Thus the intramedullary device holds advantages of a smaller incision, less soft tissue dissection, load sharing fixation and relative stability that encourages copious callus formation(12). The titanium nail has been successfully used in fixation of pediatric long bone fractures.

Another advantage of the titanium ESIN is that it can block itself in the bone and provide a three-point fixation within the S-shaped clavicle (8,13).

In a retrospective analysis between titanium elastic nails and reconstruction plates, Chen et al showed a significantly shorter time to union with the TEN group with no significant difference in non-union or

malunion rate between TEN and plating. TEN group showed a faster functional recovery with greater patient satisfaction with cosmesis and overall outcome (24).

In a randomized control trial between intramedullary nailing and non-operative treatment by Smekal et al, better DASH and Constant scores and 100% union rate with intramedullary nailing.(7) has been reported.

ANATOMY

SURGICAL ANATOMY

The clavicle is a relatively thin bone, widest at its medial and lateral expansions where it articulates with the sternum and acromion, respectively.

It has two distinct curves : The larger, obvious curve is in the coronal plane giving the bone its characteristic S shape (medial end convex anterior and lateral end concave anterior).

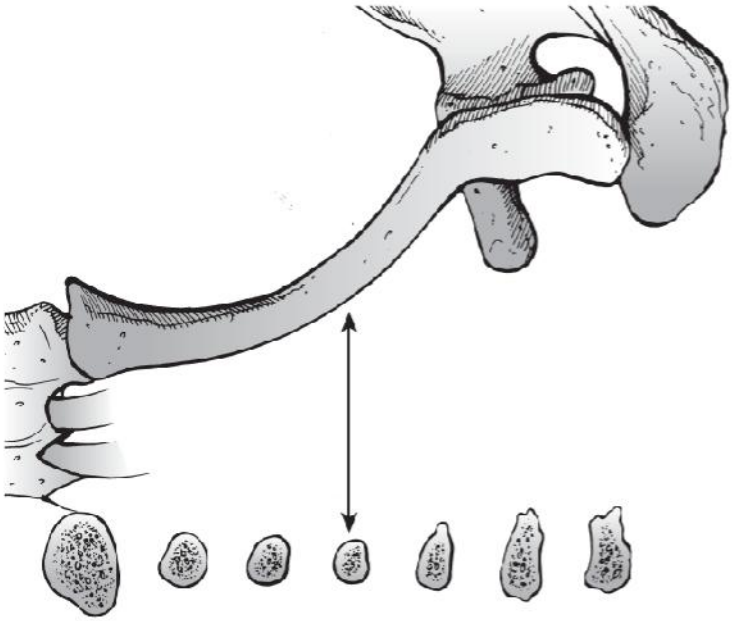


FIG-1 : The cross section and Topographic anatomy of the clavicle. The clavicle is narrowest in this midportion explaining its high incidence of fracture in this area.

LIGAMENTOUS ANATOMY:

MEDIAL:

Medially the clavicle is secured to the sternum by the Sternoclavicular capsule.

The thickening of the posterior capsule has been determined to be the single most important soft tissue constraint to anterior or posterior translation of the medial clavicle.

There is also an interclavicular ligament which runs from the medial end of one clavicle, gains purchase from the superior aspect of the sternum at the sternal notch, and attaches to the medial end of the contralateral clavicle. Acting as a tension wire at the base of the clavicle, this ligament helps prevent inferior angulation or translation of the clavicle.

In addition, there are extremely stout ligaments that originate on the first rib and insert on the undersurface or the inferior aspect of the clavicle.

A small fossa inferomedially, the rhomboid fossa, has been described as an attachment point for these ligaments, which primarily resist translation of the medial clavicle.

LATERAL:

The coracoclavicular ligaments are the trapezoid (more lateral) and conoid (more medial) which are stout ligaments that arise from the base of the coracoid and insert onto the small osseous ridge of the inferior clavicle (trapezoid) and the clavicular conoid tubercle (conoid).

These ligaments are very strong and provide the primary resistance to superior displacement of the lateral clavicle.

Clavicle fractures in this location will often have an avulsed inferior fragment to which these ligaments are attached, especially in younger individuals.

The capsule of the Acromioclavicular joint is thickened superiorly and is primarily responsible for resisting anteroposterior displacement of the joint. It is important to repair this structure, which is usually reflected surgically as part of the deep myofascial layer, when operating on the lateral end of the clavicle.

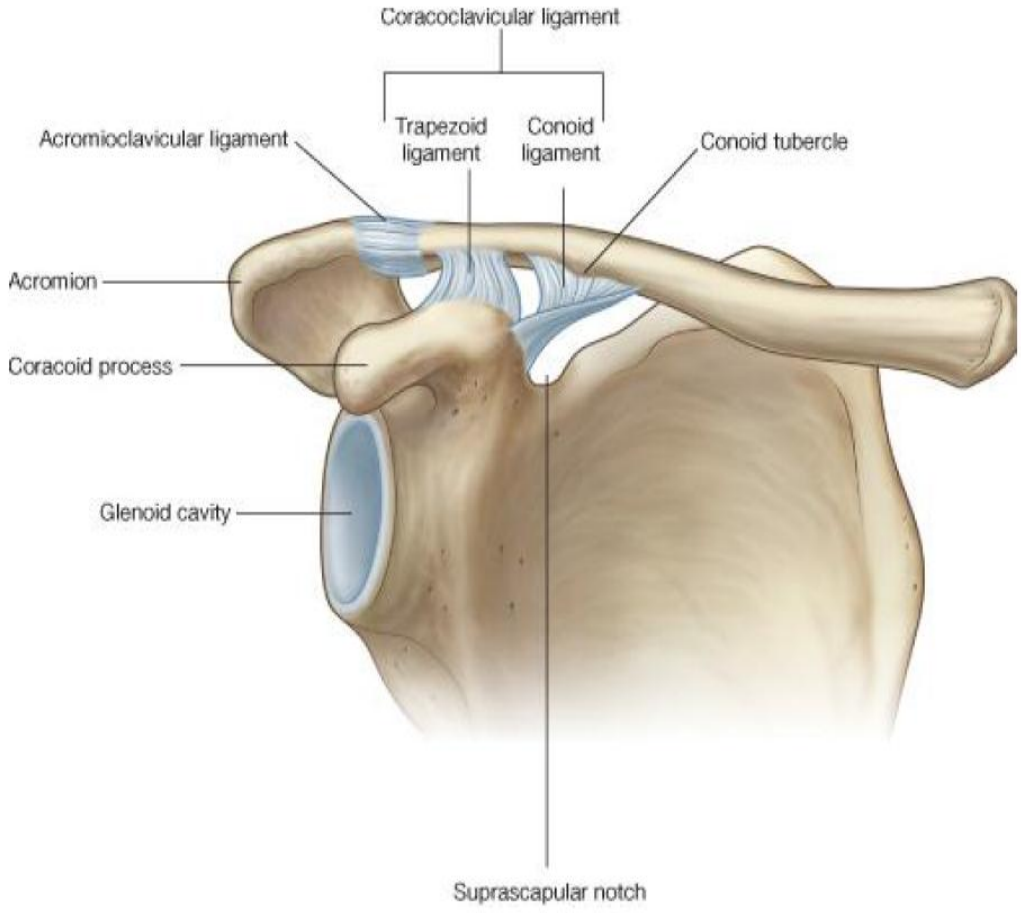


FIG-2: TRAPEZOID, CONOID, AND ACROMIOCLAVICULAR LIGAMENTS.

MUSCULAR ANATOMY OF CLAVICLE

Medially, the pectoralis major muscle originates from the clavicular shaft anteroinferiorly, and the sternocleidomastoid originates superiorly.

The pectoralis origin merges with the origin of the anterior deltoid laterally, while the trapezius insertion blends superiorly with the deltoid origin at the lateral margin.

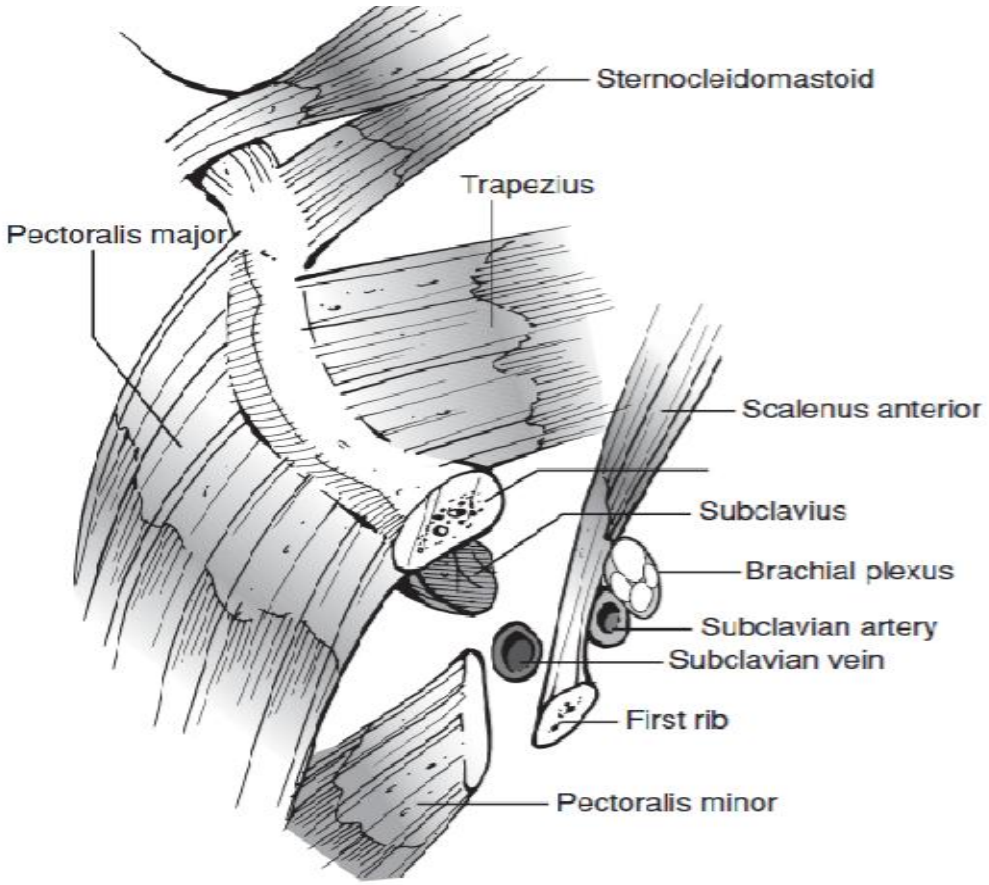


FIG-3, MUSCULAR ATTACHMENTS OF CLAVICLE

The undersurface of the clavicle is the insertion site of the subclavius muscle, serves as a soft tissue buffer in the subclavicular space superior to the brachial plexus and subclavian vessels.

NEUROVASCULAR ANATOMY OF CLAVICLE:

Supraclavicular nerves are one of the main structure on the anterior surface of clavicle. These are branches of cervical plexus. Jupiter and Ring et al reported that it is important to locate and preserve supraclavicular nerves during surgical approach to the midclavicle(26).

Most vital neurovascular structures lie inferior to the clavicle. The subclavian vein runs directly below the subclavius muscle and above the first rib.

More posteriorly lie the subclavian artery and the brachial plexus, separated from the vein and clavicle by the additional layer of the scalenus anterior muscle medially. The plexus is closest to the clavicle in its midportion.

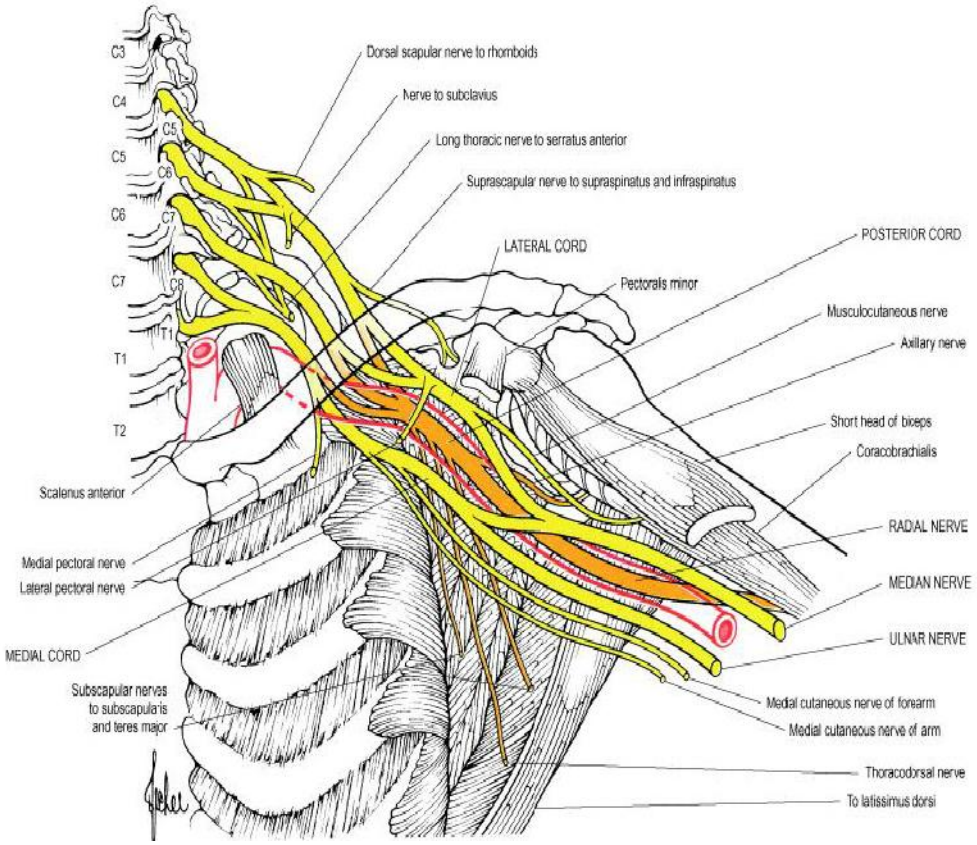


FIGURE-4, NEUROVASCULAR ANATOMY OF CLAVICLE

MECHANISM OF INJURY

A direct blow on the point of the shoulder is the commonest reported mechanism of injury that produces a midshaft fracture of the clavicle(28).

Although fall on an outstretched hand is widely believed to be the most common mechanism of injury.(27)

Direct trauma occur in a number of ways, including being thrown from a vehicle or bicycle, during a sports event, from the intrusion of objects or vehicle structure during a motor vehicle accident, or falling from a height(28).

It is independent of muscular forces or arm position and all regions of the clavicle are vulnerable.

A recent prospective trial of over 130 completely displaced midshaft fractures of the clavicle identified motor vehicle / motorcycle accidents, bicycling accidents, skiing/snowboarding falls or collisions, sports injuries, and falls as the most commonly involved mechanisms.

Simple falls from a standing height are unlikely to produce a displaced fracture in a healthy young person, but can result in injury in elderly, osteoporotic individuals.

These fractures are typically seen in the distal third of the clavicle.

FRACTURE BIOMECHANICS:

The direction of the initial deforming force, and both gravitational and muscular forces on the clavicle are significant and result in the typical deformity seen after fracture, with the distal fragment being translated inferiorly, anteriorly, and medially(shortened), and rotated anteriorly.

The medial clavicular fragment is elevated by the unopposed pull of the sternocleidomastoid muscle, while the distal fragment is held inferiorly by the deltoid and medially by the pectoralis major.

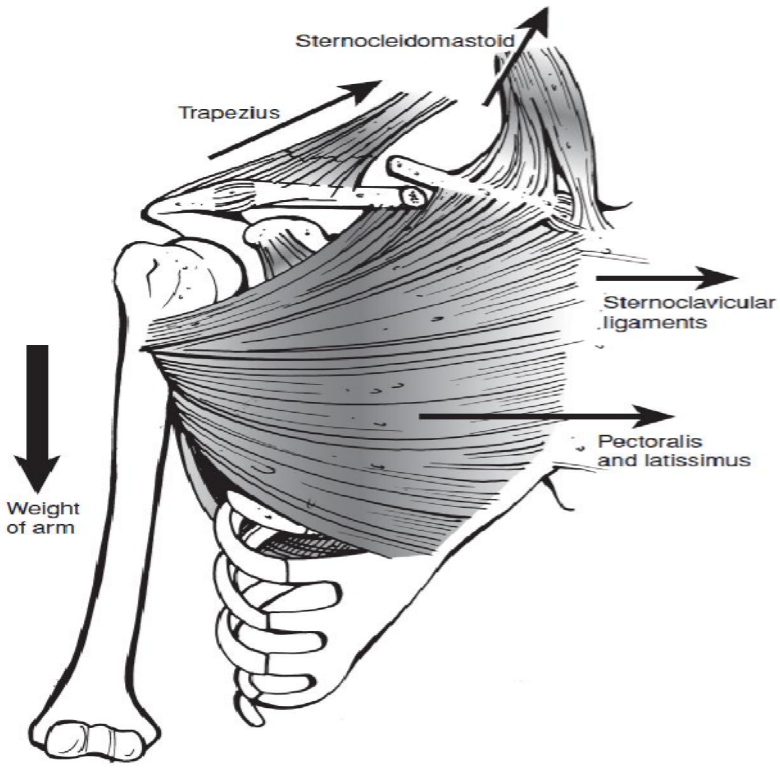


FIGURE-5, MUSCULAR AND GRAVITATIONAL FORCES ACTING ON THE CLAVICLE

CLASSIFICATION

A number of classification schemes have been proposed for fractures of the clavicle. These have traditionally been based on the position of the fracture.

Originally divided by ALLMAN into

GROUP I : Middle third

GROUP II : Lateral third

GROUP III : Medial third

Neer divided **distal** clavicle fractures into three subgroups, based on their ligamentous attachments and degree of displacement.

(Type II was subsequently modified by **Rockwood**)

Type I : Distal clavicle fracture with the coracoclavicular ligaments intact.

Type II : Coracoclavicular ligaments detached from the medial fragment, with the trapezoidal ligament attached to the distal fragment

IIA (Rockwood): Both conoid and trapezoid attached to the distal fragment

IIB (Rockwood): Conoid detached from the medial fragment

Type III: Distal clavicle fracture with extension into the AC joint.

ROBINSON CLASSIFICATION OF CLAVICULAR FRACTURES

(Figure 6)

TYPE 1 – MEDIAL CLAVICE

A - fracture is nondisplaced

A1 – extraarticular

A2 – intraarticular

B - fracture isdisplaced

B1 - extraarticular

B2 - intraarticular

TYPE 2 – MIDDLE CLAVICLE

A - cortical alignment

A1 - nondisplaced

A2 - angulated

B-displaced fracture

B1- consists of simple or single butterfly fragment

B2- is a comminuted or segmental fracture.

TYPE 3-DISTAL CLAVICLE

A-nondisplaced fracture

A1 - extraarticular fracture

A2 - intraarticular fracture

B-displaced fracture

B1 - extraarticular fracture

B2 - intraarticular fracture

CRAIG CLASSIFICATION (Figure 6)

GROUP I : Middle third fracture.

GROUP II : Distal third fracture.

TYPE I - minimal displacement (interligamentous)

TYPE II - displaced occurs secondary to fracture with fracture medial to the coracoclavicular ligaments.

(A) Conoid and trapezoid remains intact.

(B) Conoid is torn but trapezoid remains intact.

TYPE III - Intra articular fractures.

TYPE IV - periosteal sleeve fracture as seen in children.

TYPE V - comminuted fracture with ligaments attached to the comminuted fragment.

GROUP III : Fractures of the proximal third

TYPE I - minimal displacement

TYPE II - displaced (ligaments ruptured)

TYPE III - intra-articular

TYPE IV - epiphyseal separation (children and young adults)

TYPE V – comminuted.

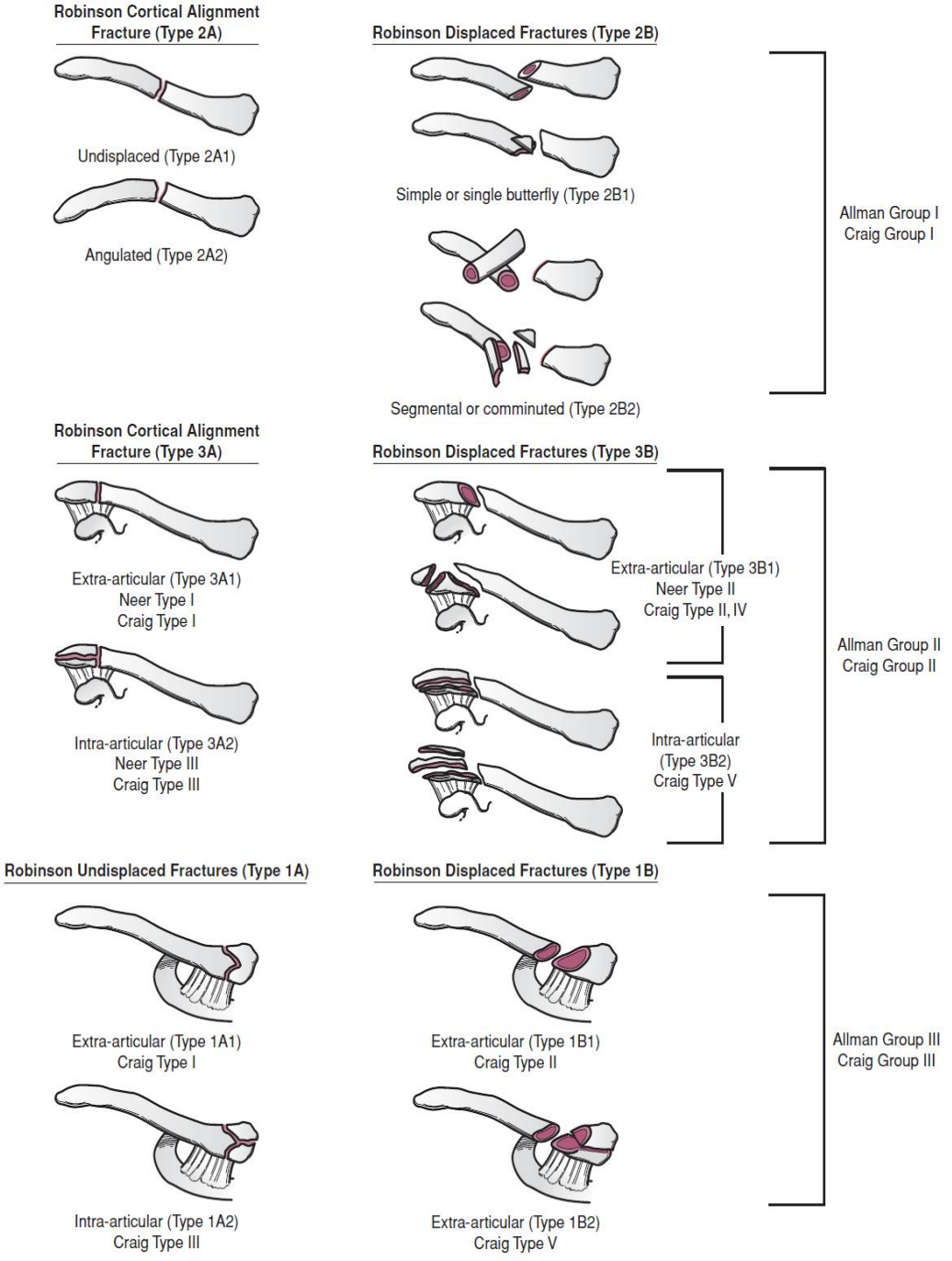
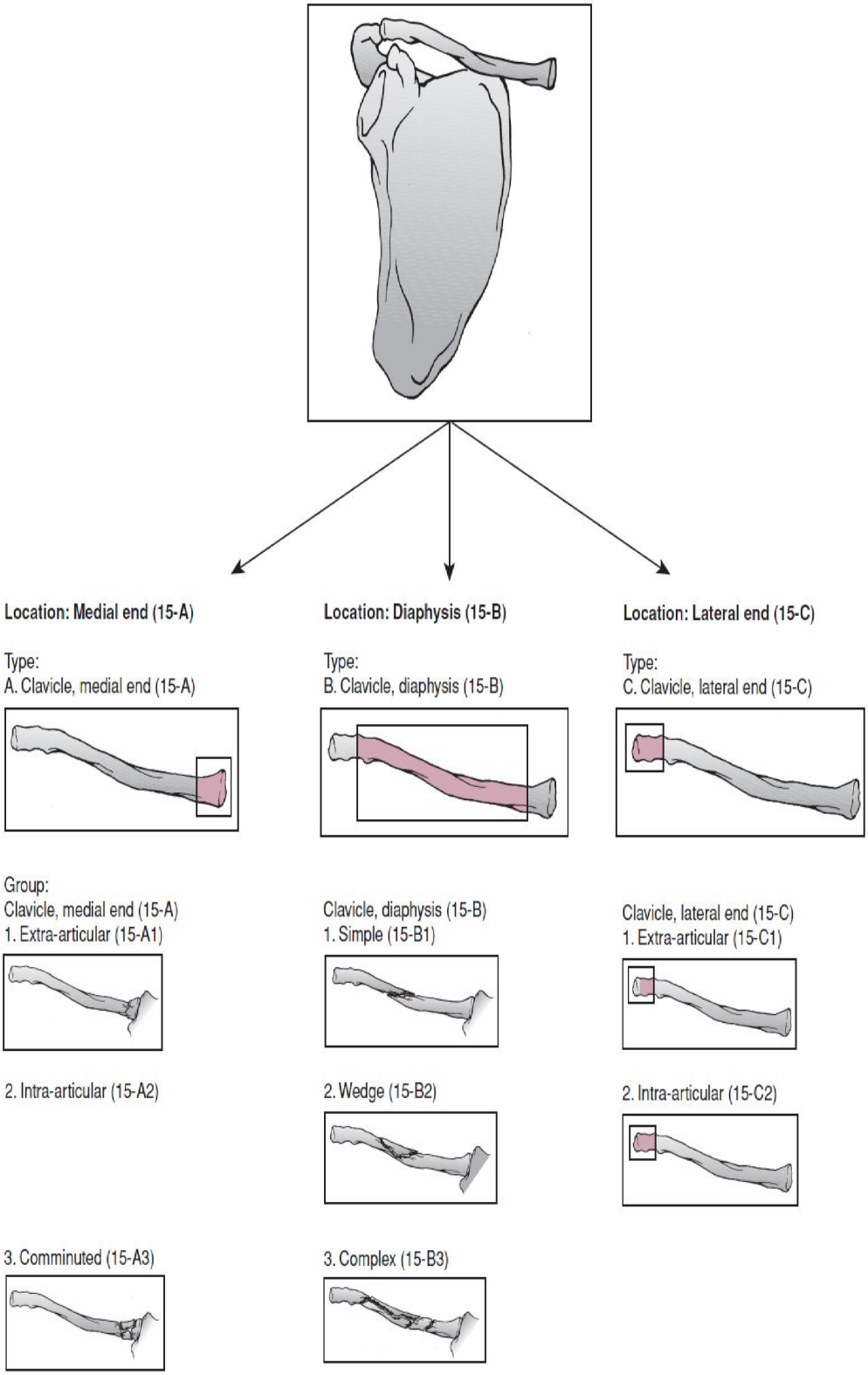


FIG-6, ALLMAN, CRAIG AND ROBINSON CLASSIFICATION.

AO/OTA CLASSIFICATION OF CLAVICLE FRACTURES



TREATMENT OPTIONS

VARIOUS TREATMENT OPTIONS

NON OPERATIVE TREATMENT:

The earliest reported attempt at closed reduction of a displaced midshaft fracture of the clavicle was recorded in the “Edwin Smith” papyrus dating from the 30th century BC.

Hippocrates described the typical deformity resulting from this injury, and emphasized the importance of trying to correct it.(29)

It is possible to obtain an improvement in position of the fracture fragments by placing the patient supine, with a roll or sandbag behind the shoulder blades to let the anterior displacement and rotation of the distal fragment correct with gravity, followed by superior translation and support of the affected arm. Unfortunately, it is difficult or impossible to maintain the reduction achieved.

Over the millennium that followed the first description of treatment of this fracture, there have been hundreds of descriptions of different devices designed to maintain the reduction, including splints, body jackets, casts, braces, slings, swathes, and wraps.(29,30,31,31)

At the present time, there is no convincing evidence that any of these devices reliably maintains the fracture reduction or improves clinical, radiographic, or functional outcomes.

Immobilization with figure of 8 bandages have been main standard of care in non operative management.

OUTCOMES:

Recent studies have shown that the union rate for displaced midshaft fractures of the clavicle may not be as favorable as previously described.

In a prospective series of 868 patients with clavicle fractures treated nonoperatively, Robinson et al.(33) reported a significantly higher nonunion rate (21%) in displaced comminuted midshaft fractures.

McKee et al, reported on a series of patients who has nonoperative treatment of a displaced midshaft clavicle fracture a mean of over 4 years earlier.

Objective muscle strength testing revealed significant strength deficits, especially of shoulder abduction and flexion which help explain some of the patient dissatisfaction seen despite bony union.(37)

OPERATIVE TREATMENT:

Primary operative treatment of clavicle fractures are usually indicated in the following Conditions,

FRACTURE SPECIFIC:

1. Displacement >2 cm
2. Shortening >2 cm
3. Increasing comminution (>3 fragments)
4. Segmental fractures
5. Open fractures
6. Impending open fractures with soft tissue compromise
7. Obvious clinical deformity with shoulder asymmetry
8. Scapular malposition and winging on initial examination

ASSOCIATED INJURIES:

1. Vascular injury requiring repair
2. Progressive neurologic deficit
3. Ipsilateral upper extremity injuries fractures

4. Multiple ipsilateral upper rib fractures

5. Floating shoulder

6. Bilateral clavicle fractures

PATIENT FACTORS:

1. Polytrauma with requirement for early upper extremity weight-bearing/arm use
2. Patient motivation for rapid return of function (e.g., elite sports or the self-employed professional).

METHODS OF OPERATIVE TREATMENT:

OPEN REDUCTION AND PLATE OSTEOSYNTHESIS

Advantages

- Rigid fixation
- Cortical compression can be achieved
- Provides rotational control
- Restoration of length and alignment of clavicle is good.

Disadvantages

- Large wound size and scar
- Hardware irritation
- Supraclavicular nerve injury
- Chance of infection

IMPLANTS AVAILABLE:

1. Reconstruction plate
2. Locking reconstruction plate
3. Precontoured superior and anterior locking compression plate

OPEN/CLOSED REDUCTION AND INTRAMEDULLARY FIXATION:

Advantages:

- Can be performed closed.
- Limited exposure with minimal soft tissue disruption.
- Implants can be removed under local anaesthesia.

Disadvantages

- Infection.
- Hardware prominence and migration.
- Does not provide rotational control
- Nonunion.

IMPLANTS AVAILABLE:

- Titanium elastic nail
- Hagie pin
- Intramedullary compression clavicular nail

EXTERNAL FIXATION:

1954 - **COOK. T.W** described external fixation for infected clavicle fractures.

- Reports available in literature on the use of external fixator is very less.
- Indications were open fracture, severe soft tissue injury with risk of soft tissue necrosis

MATERIALS AND METHODS

The study was formally approved by Hospital ethics committee. This prospective study of functional outcome of displaced midshaft clavicle fractures treated by intramedullary titanium elastic nail system was done at the Department of Orthopaedics, Government kilpauk Medical College Hospital, Chennai from September 2013 to July 2015.

INCLUSION CRITERIA:

A Total of 20 patients who meet the following criterias are included in the study,

- All skeletally mature patients.
- All the displaced diaphyseal non comminuted/simple comminution clavicle fractures(>2cm displacement) – AO 15 B1 and B2 fractures.
- Fractures with shortening of over 20 mm
- Fractures within one week

EXCLUSION CRITERIA:

- Fractures with marked comminution.
- Brachial plexus injuries
- Fractures older than 1 week
- Paediatric fractures
- Pathological fractures
- Open fractures
- Congenital anomaly or bone disease.
- Any medical contraindication for surgery.

All the patients were admitted and required skeletal survey were done and other injuries ruled out. The patient were initially immobilized by figure of eight bandage, Until the patient gets assessed for surgery.

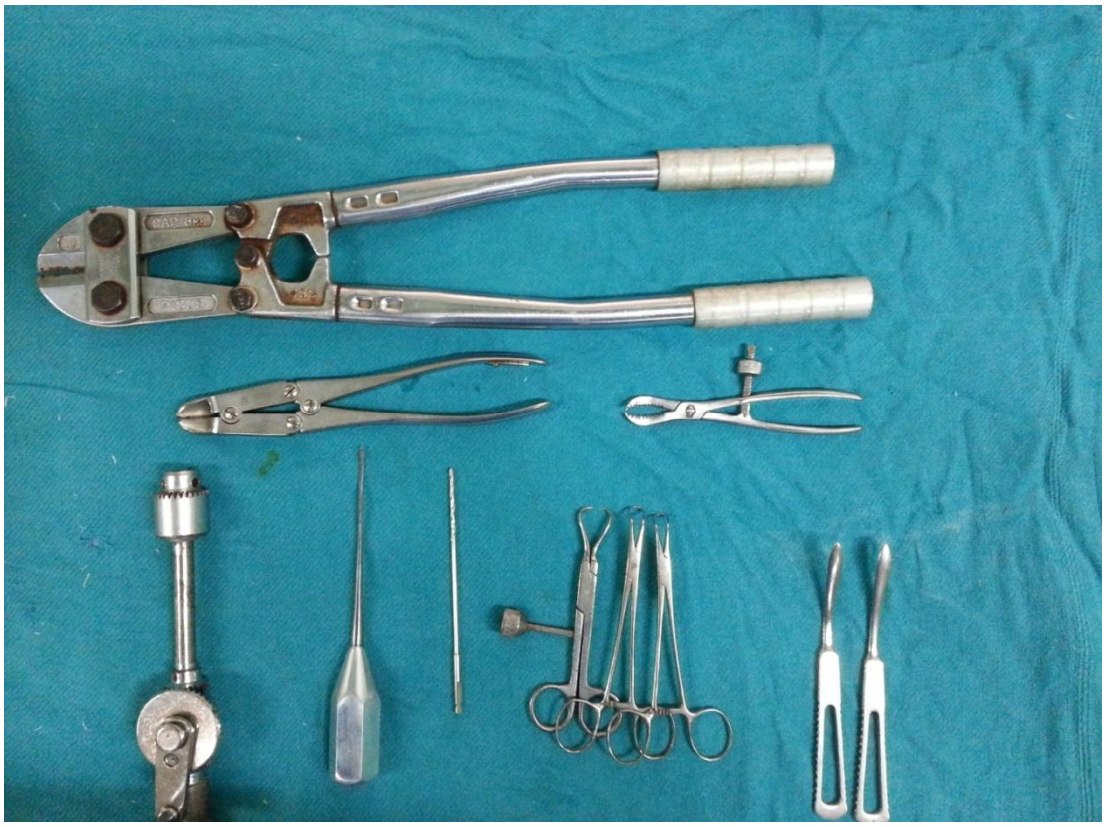
The following preoperative evaluations are done.

1. Radiological: Plain x-ray of the affected shoulder Antero-Posterior view and 30 degree cephalic tilt view if needed.
2. Complete hemogram

3. Renal function test
4. Bleeding time and clotting time
5. Screening for HIV, Hepatitis B & C, Syphilis
6. Chest X-ray and Electrocardiogram.

If the patients had any other comorbidities, concerned specialist opinion are obtained prior to surgery.

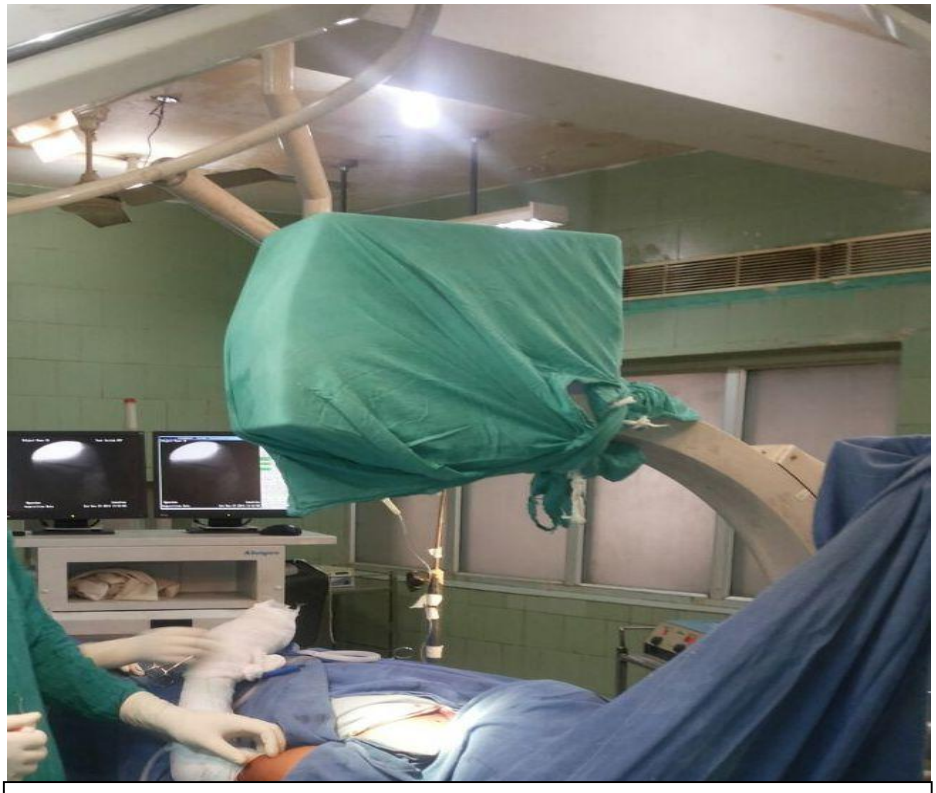
SURGICAL INSTRUMENTS



1. 2.7 mm drill bit
2. Bone awl
3. Titanium elastic nail(various sizes- 2, 2.5, 3mm)
4. T-handle
5. Reduction clamps
6. Hohmans Spike
7. Nail Cutter

SURGICAL TECHNIQUE: INTRAMEDULLARY TITANIUM ELASTIC NAIL SYSTEM FOR MIDSHAFT CLAVICLE FRACTURES.

After administration of anaesthesia (either general / regional), the patient was placed in supine position on radiolucent table with a sandbag under ipsilateral shoulder. The injured extremity prepared and draped from the midline to the upper arm. Care was taken to make sure that the sternoclavicular joint was accessible for the entry point. Preoperatively, the shoulder region was screened using image intensifier to confirm this access.



Patient position after draping with c-arm perpendicular to the table and monitor at foot end

APPROACH:

A one cm horizontal incision was made just lateral to the sternoclavicular joint. The subcutaneous fat was incised along with platysma.

The pectoral fascia was divided in line with the skin incision followed by careful elevation of the underlying musculature from the clavicle.

The entry point was then made using the awl directly or can be pre-drilled with a 2.7mm drill bit to make a foot print.

Appropriate sized titanium ESIN, after being loaded in T-handle was inserted (The size of the nail was measured using this formula = 0.4 × canal diameter in mm).

Under fluoroscopic control, attempt was made to close reduce the fracture. Two percutaneously used reduction clamps can be used to aid in reduction.

If the fracture could not be reduced by closed means, then a separate mini open incision was used at the fracture site for direct manipulation of fragments.

At that time, the nail was used to create a path in the lateral end of the clavicle for subsequent easy access. The nail was then passed from the medial side and across the reduced fracture into the lateral end of clavicle until it is just medial to the acromio clavicular joint.

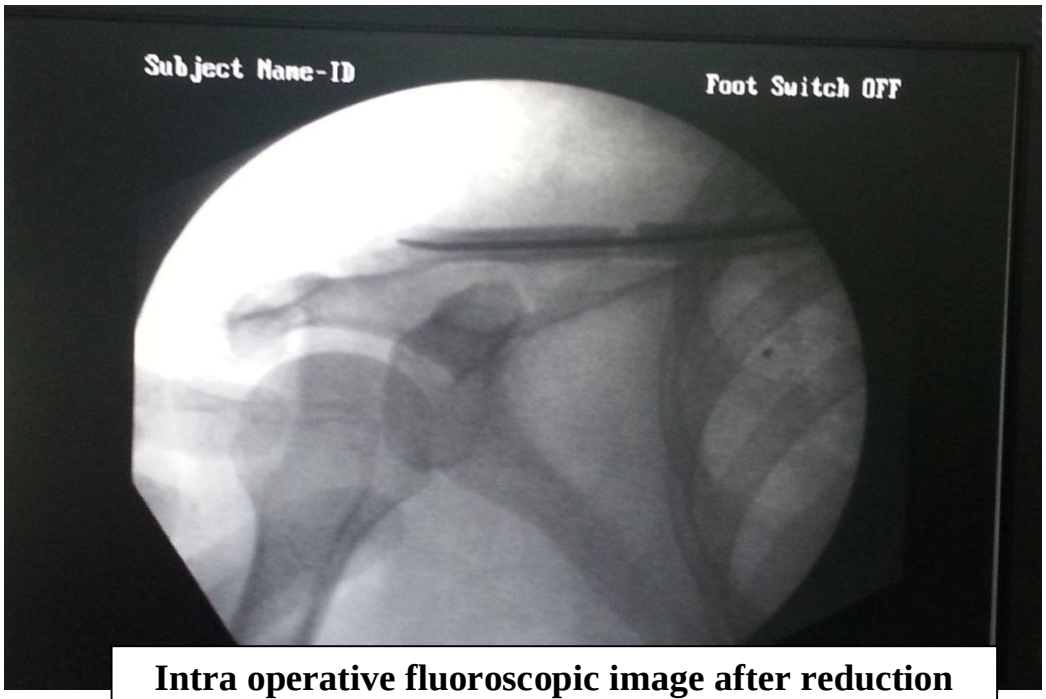
After reaching the endpoint, the nail is cut close as to prevent soft tissue irritation but leaving behind sufficient length for the extraction to be easy later on. The fascia and skin were closed in layers.

Skin incision lateral to SC joint

Entry with bone awl

Insertion of TENS nail with a T-handle

Manipulation under fluoroscopic control



Intra operative fluoroscopic image after reduction

After wound closure

POST OPERATIVE PROTOCOL:

Postoperatively, patients were given a sling, but were encouraged for early shoulder mobilization as tolerated.

Pendular exercises for the shoulder were started from the second day. And all the patients were discharged on the second postoperative day.

After 7 days, active range of movement exercises were started, however, overhead shoulder abduction was allowed only after 2 weeks.

The sling was discarded at around 2 weeks, thereafter activities of daily living were started, but those requiring lifting heavy objects were delayed until radiological and clinical union was achieved.

All patients were reviewed in the outpatient department at 2 and 6 weeks, 3, 6,12 months after surgery. At each visit, patients were assessed clinically and radiologically for primary and secondary outcome measures.

OUTCOME ASSESSMENT:

Functional outcome was assessed by the Constant score. Radiographic union was defined as evidence of bridging callus or obliteration of fracture lines.

Clinical union was considered as absence of tenderness at the fracture site. Time to achieve union was recorded. After union, shortening of clavicular length was measured clinically as the linear difference of clavicle lengths from sternal end to acromial end between operated and normal side.

Secondary outcome measures include perioperative data like operative time, amount of blood loss and size of the surgical wound; complications such as neurovascular injury, wound infection, nonunion, malunion, implant migration, implant failure, soft tissue irritation, refracture after implant removal and cosmetic outcome with regards to visible deformity, scars and hardware prominence under the skin. Implant removal was done routinely in our study.

CONSTANT SCORE TECHNIQUE

This scoring system consists of four variables that are used to assess the function of the shoulder. The right and left shoulders are assessed separately.

The subjective variables are pain and ADL (sleep, work, recreation / sport) which give a total of 35 points. The objective variables are range of motion and strength which give a total of 65 points.

SUBJECTIVE

Pain	15
ADL (sleep, work, recreation/sport)	20

OBJECTIVE

Range of motion	40
Strength	25

RANGE OF MOTION

Active range of motion should always be measured as part of the Constant Score. There is specific way recommended by ESSES (European Society for Shoulder and Elbow Surgery) for measuring range of motion. Patient should be sitting on a chair or bed, with weight evenly

distributed between the ischialtuberosities. No rotation of the upper body should take place during the examination.

In case of active motion, the patient lifts his arm to a pain free level. The range of motion is determined by the number of degrees at which the pain starts. If one measures the active range of motion with pain, this should be stated. The Constant score cannot be applied beyond the initiation of pain.

In the Constant score system there is precise information given about how the points should be calculated. Keep in mind that 150 degrees of flexion give 8 points, while 151 degrees give 10 points.

Forward flexion 10 points

0-30	0
31-60	2
61-90	4
91-120	6
121-150	8
151-180	10

Abduction 10 points

0-30	0
31-60	2
61-90	4
91-120	6
121-150	8
151-180	10

External rotation 10 points (hand is not allowed to touch the head)

Not reaching the head	0
Hand behind head with elbow forward	2
Hand behind head with elbow back	2
Hand on top of head with elbow forward	2
Hand on top of head with elbow back	2
Full elevation from on top of head	2

Internal rotation 10 points

End of the thumb to lateral thigh	0
End of the thumb to buttock	2
End of the thumb to lumbosacral junction	4
End of the thumb to L3 (waist)	6
End of the thumb to T 12	8
End of the thumb to T 7(interscapular)	10

STRENGTH

Strength is given a maximum of 25 points in the Constant Score. The significance and technique of strength measurement has been, and continues to be, the subject of much discussion.

The European Society for Shoulder and Elbow Surgery measures strength according to the following method:

- A spring balance is attached distal on the forearm.
- Strength is measured by keeping the arm in 90 degrees of elevation in the plane of the scapula (30 degrees in front of the coronal plane) and elbow should be straight.

- Palm of the hand should be facing the floor (pronation).

The patient should be asked to maintain this resisted elevation for 5 seconds.

- It should be repeated 3 times immediately one after another.
- The average in pound should be (lb) is noted.
- The measurement should be pain free. If pain is involved the patient gets 0 points.
- If patient is unable to achieve 90 degrees of elevation in the scapula plane the patient gets 0 points.

0 = Less than 1 kg

3 = 1 kg - 2 kg

5 = 2 kg - 3 kg

7 = 3 kg - 4 kg

9 = 4 kg - 5 kg

11 = 5 kg - 6 kg

13 = 6 kg - 7 kg

15 = 7 kg - 8 kg

17 = 8 kg - 9 kg

19 = 9 kg - 10 kg

21 = 10 kg - 11 kg

23 = 11 kg - 12 kg

25 = 12 kg or above

SCORING

0-55 - POOR

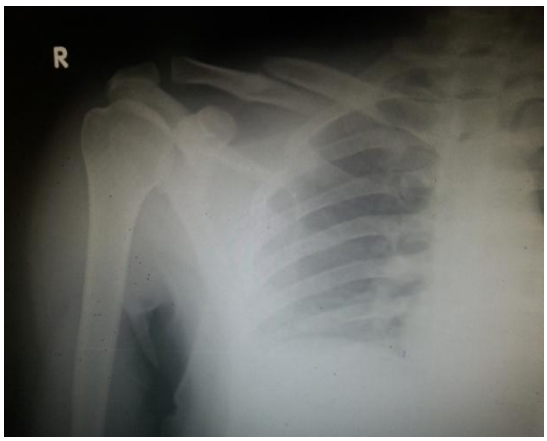
56-70 - MODERATE

71-85 - GOOD

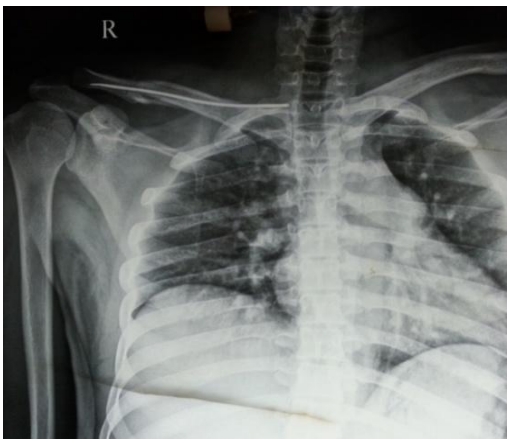
>85 - EXCELLENT

CASE REPORTS

CASE-1

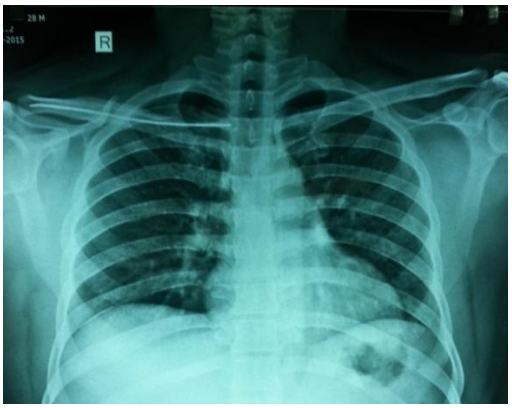


PREOPERATIVE XRAY

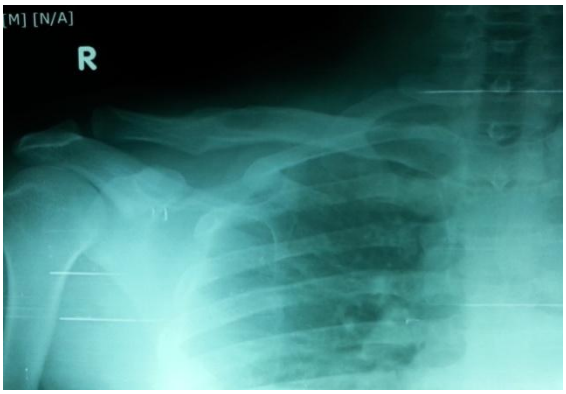


IMMEDIATE POST-OP

6 WEEKS



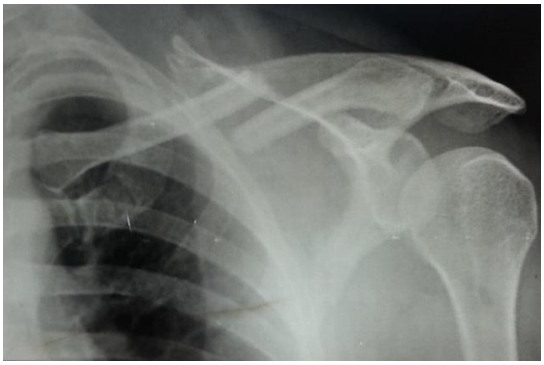
6 MONTHS POST OP



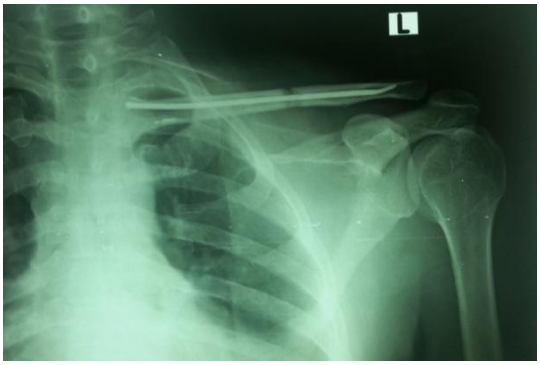
AFTER REMOVAL

POSTOPERATIVE RANGE OF MOVEMENTS

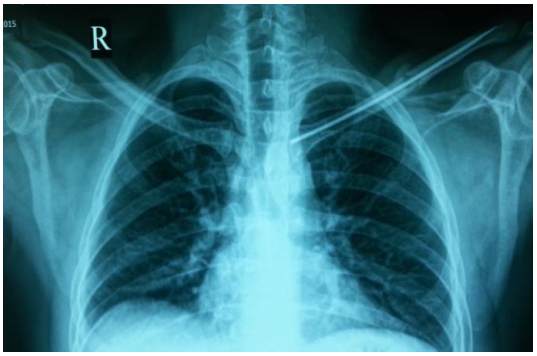
CASE-2



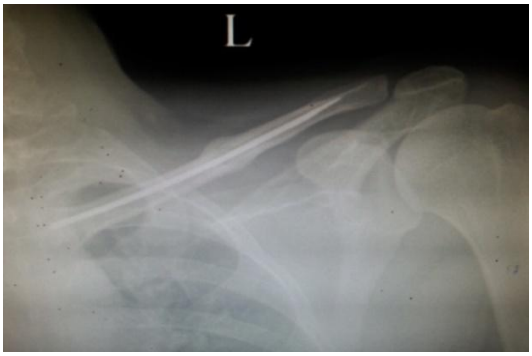
PRE- OPERATIVE XRAY



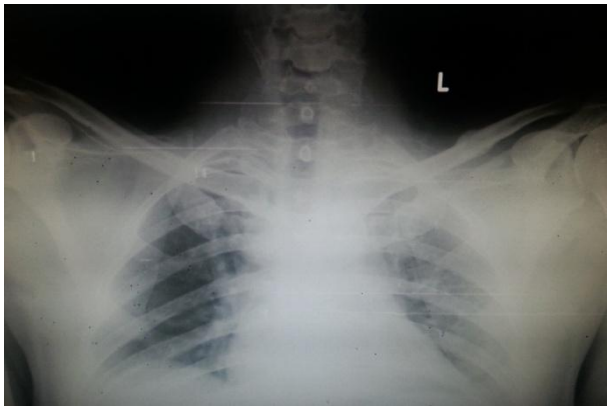
IMMEDIATE-POST OP



1 MONTH POST OP



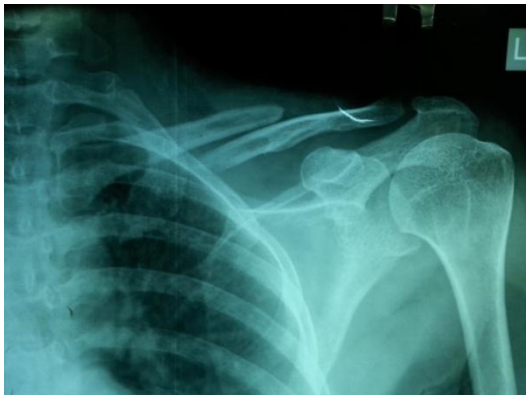
8 MONTHS POST OP



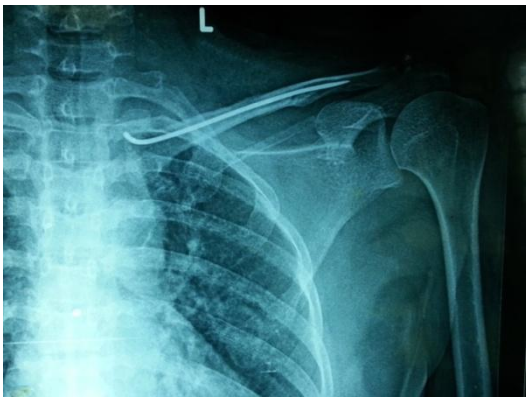
AFTER REMOVAL

POSTOPERATIVE RANGE OF MOVEMENTS

CASE-3



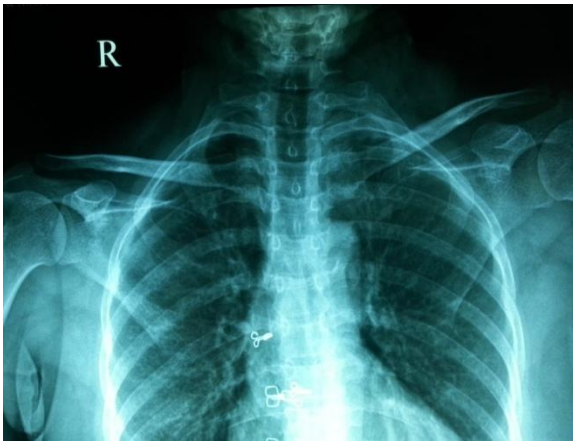
PRE-OPERATIVE X-RAY



IMMEDIATE-POST OP

6 WEEKS POST OP

3 MONTHS POST OP



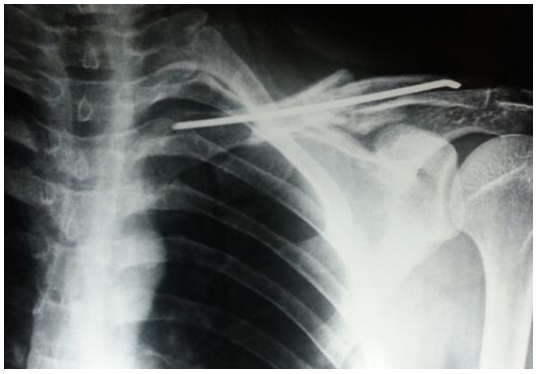
AFTER REMOVAL

CASE-4

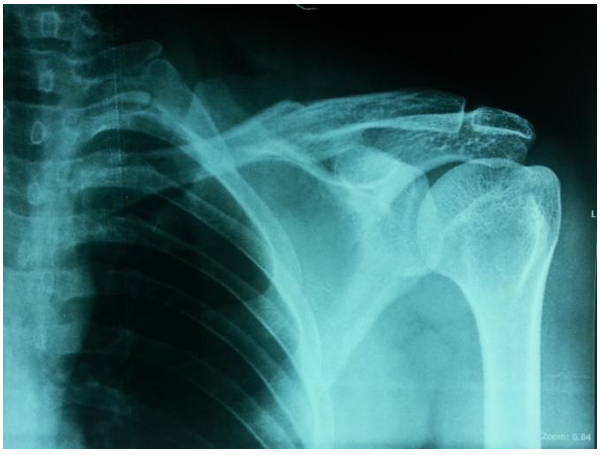
PRE-OP

IMMEDIATE POST OP

1 MONTH POST OP



3 MONTHS POST OP



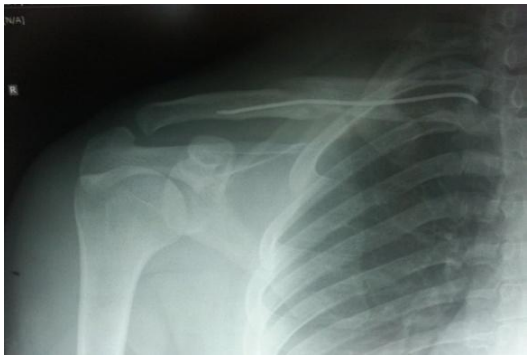
AFTER REMOVAL

POSTOPERATIVE RANGE OF MOVEMENTS

CASE-5

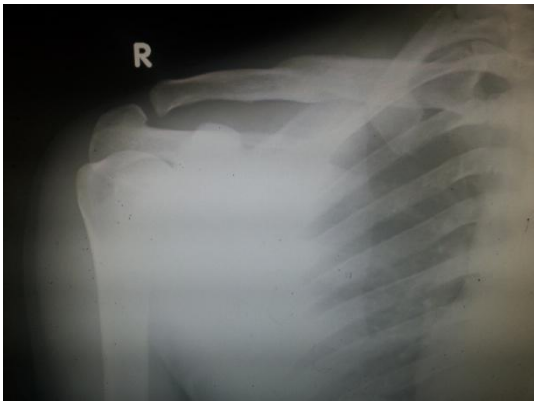
PREOP XRAY

IMMEDIATE POST OP



3 MONTHS POST OP

8 MONTHS POST OP



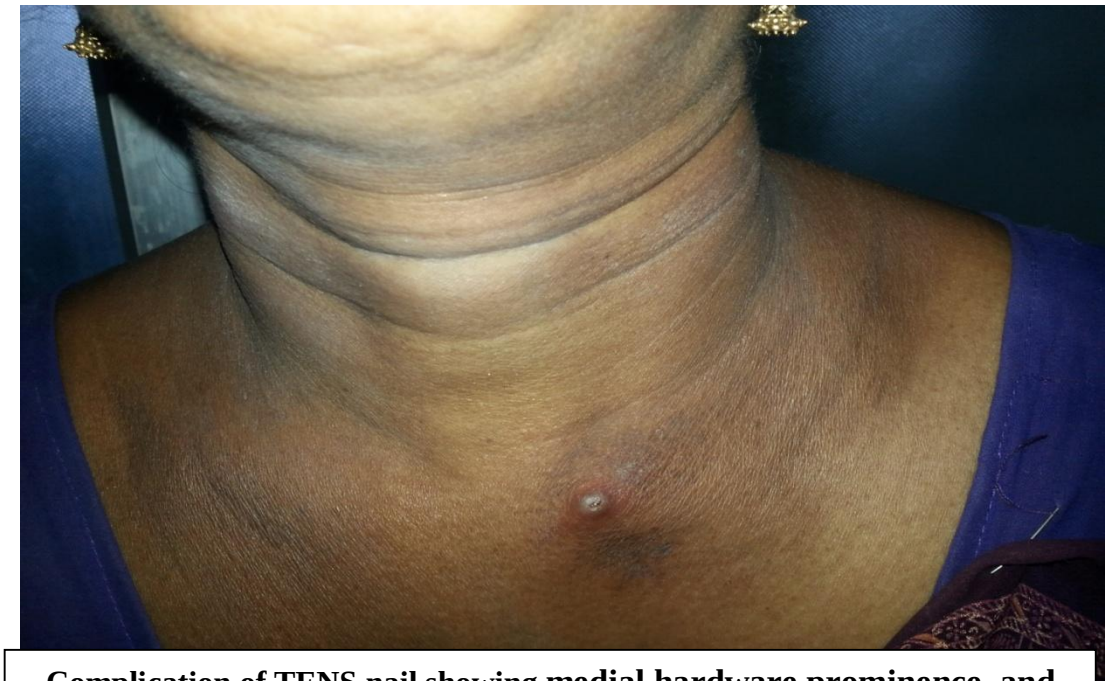
AFTER REMOVAL

POSTOPERATIVE RANGE OF MOVEMENTS

COMPLICATIONS

CASE 3: Medial Hard ware prominence and local skin perforation.

This 45 yr old female had medial implant prominence and local infection which was treated with antibiotics. But the implant has to be removed at about 3 months post op when she presented with skin perforation. By the time the fracture had united both clinically and radiologically resulting in no complications after implant removal.

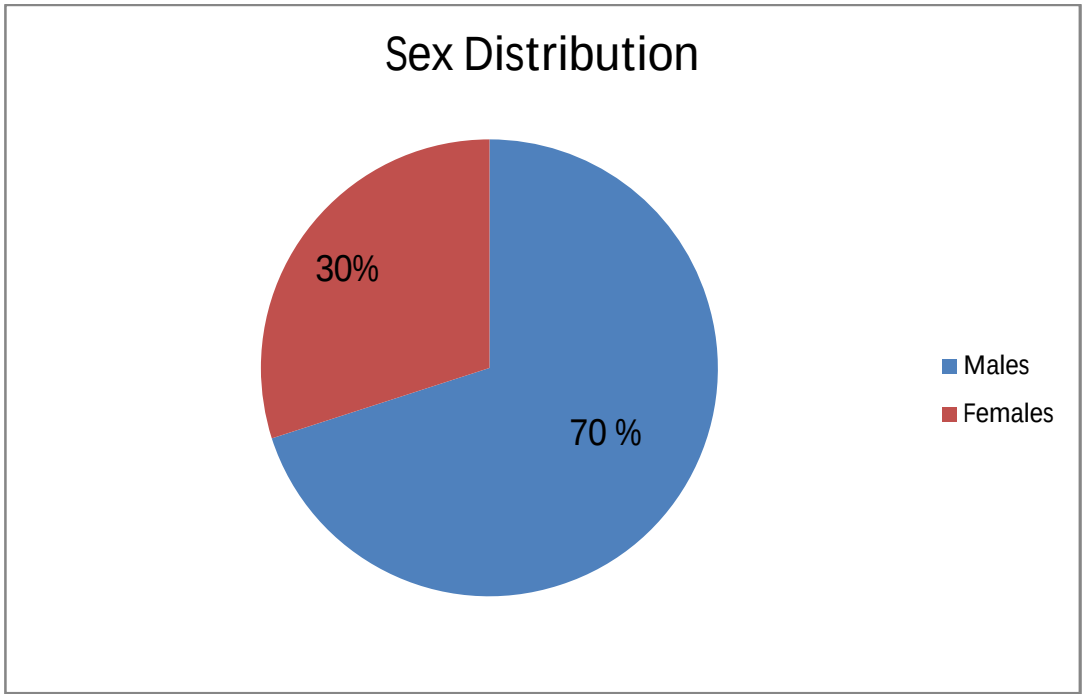


Complication of TENS nail showing medial hardware prominence and local skin perforation

OBSERVATION

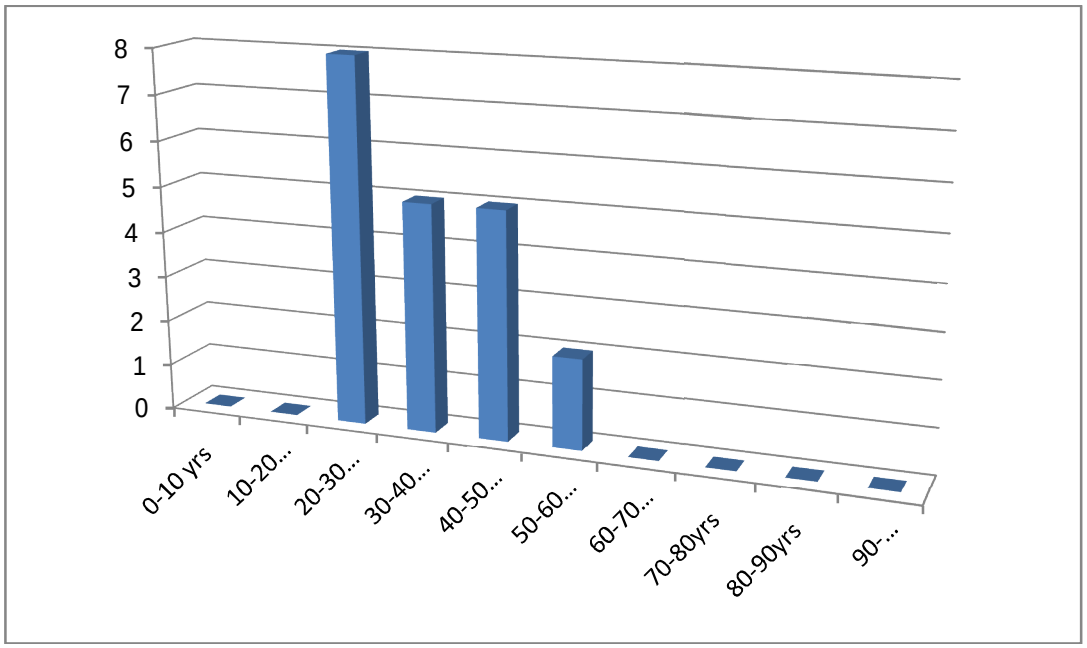
The patient demographics involved in the study is as follows.

The study included a total of 20 patients, among them there were 14 males and 6 females.



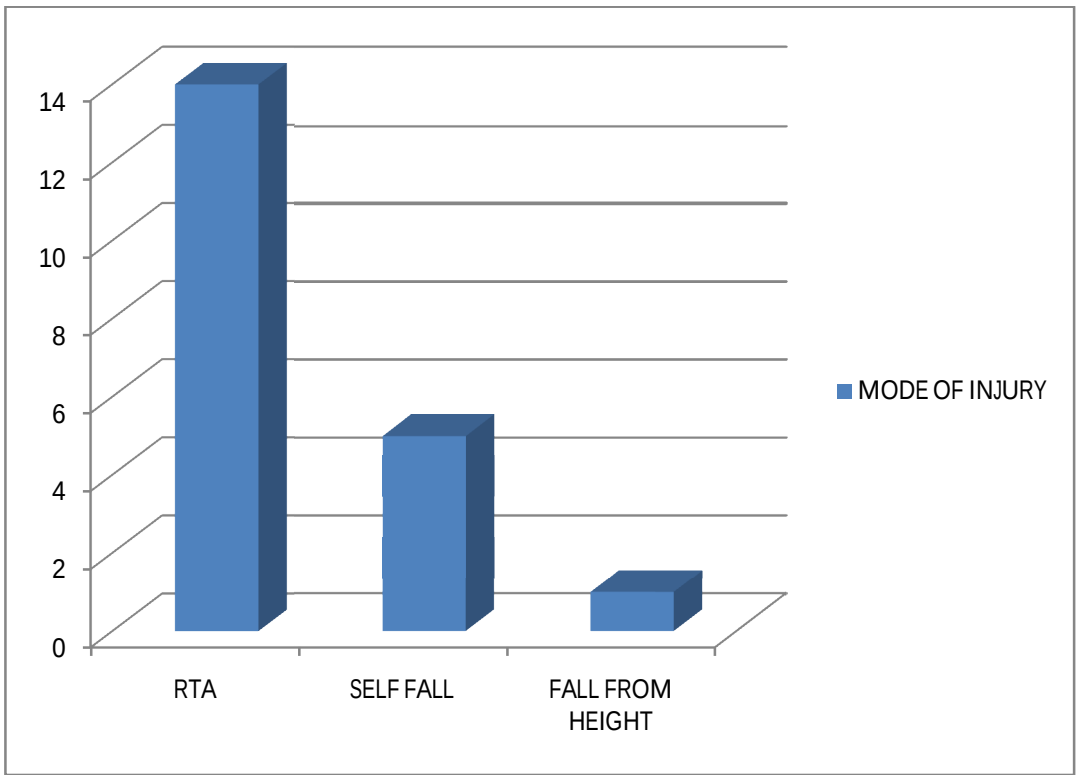
AGE DISTRIBUTION

In our study, the maximum no. of patients were in the 20 -30 yrs age group.



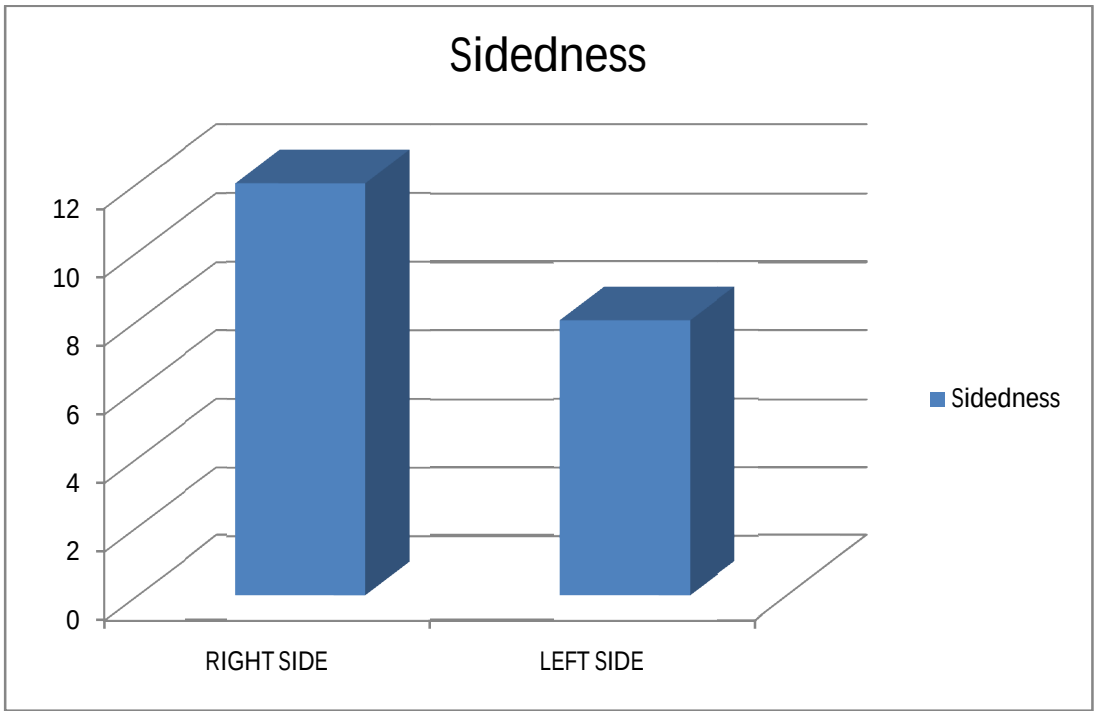
MODE OF INJURY:

The maximum number of cases were due to Road traffic accidents.



SIDEDNESS OF INJURY:

Right side involvement was more in the study patients, with 12 patients involving right clavicle and 8 patients left clavicle.



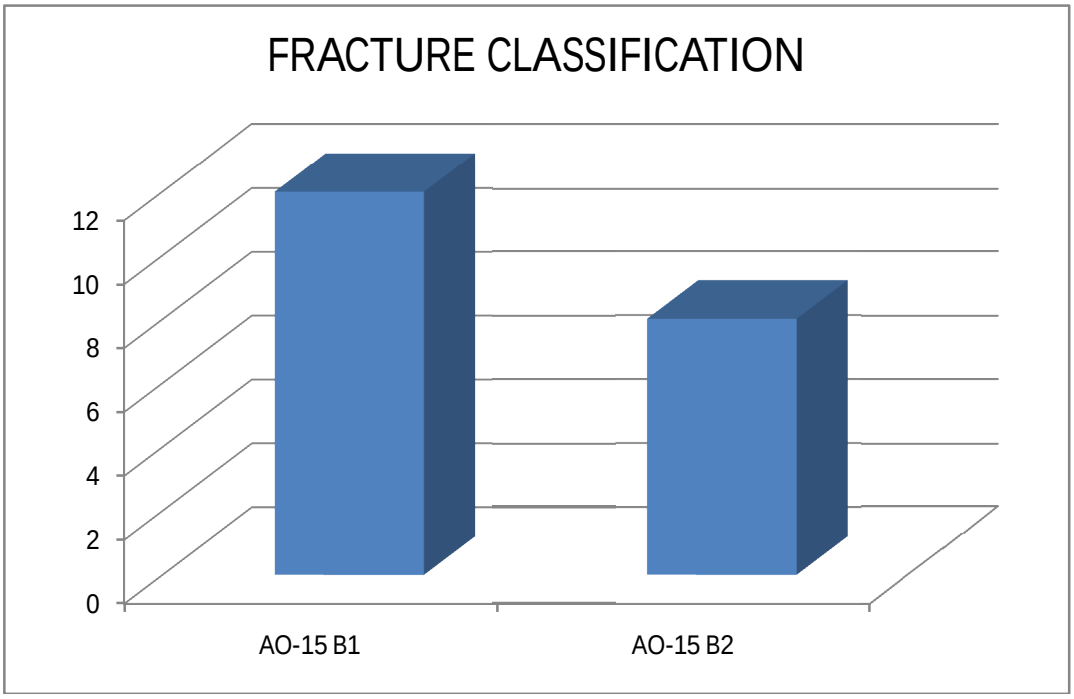
ASSOCIATED INJURIES:

In the study group, we had only two patients with associated injuries, which included- One case of ipsilateral spine of scapula fracture and another case with ipsilateral fracture both bone leg, both of them were addressed simultaneously.

FRACTURE CLASSIFICATION:

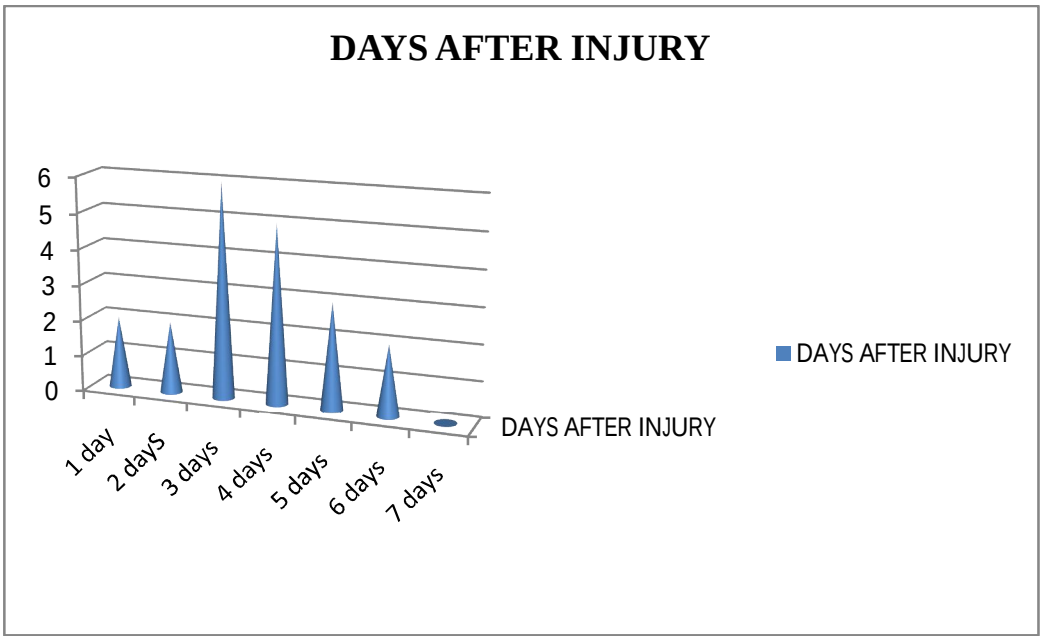
All the fractures were classified according to the AO classification.

12 patients belong to AO B1 type (Diaphysis simple) and 8 patients belong to AO B2 type (Diaphysis wedge).

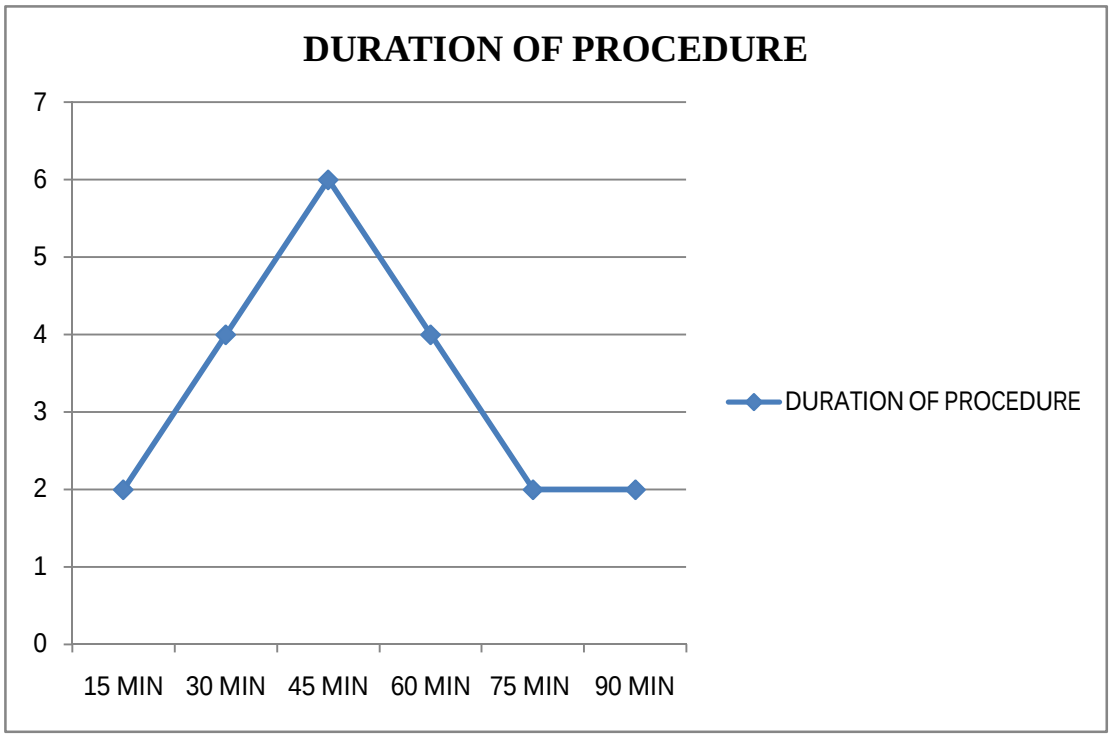


TIMING OF SURGERY:

All the patients were operated within 7 days after injury, most of the cases within 3 days.



OPERATIVE TIME:



The mean surgical time for the procedure is 49.5 minutes, ranging from 15 to 90 minutes.

RESULTS

EVALUATION OF PAIN:

Pain scale	Points	No. of patients	
		At 3 months	At 6 months
No pain	5	12(60%)	17(85%)
Mild pain	4	6(30%)	2(10%)
Pain after unusual activities	3	2(10%)	1(5%)
Pain at rest	2		
Marked pain	1		
Complete disability	0		

RANGE OF MOVEMENTS:

S.NO.	Shoulder movements	Average (mean ± standard deviation)
1.	Flexion	165.75 ± 9.21
2.	Abduction	166.25 ± 10.49
3.	External rotation	72.5 ± 6.5
4.	Internal rotation	74.25 ± 5.19

MUSCLE STRENGTH:

S.NO	MUSCLE STRENGTH	NO. OF PATIENTS	
		At 3 months	At 6 months
1.	Normal	15(75%)	18(90%)
2.	Against resistance	5(25%)	2(10%)
3.	Against gravity	-	-
4.	Elimination of gravity	-	-
5.	Flicker	-	-
6.	Paralysis	-	-

OCCUPATION LIMITATIONS:

S.NO	OCCUPATION STATUS	NO. OF PATIENTS	
		At 3 months	At 6 months
1.	Regular work	15(75%)	18(90%)
2.	Restricted work	5(25%)	2(10%)
3.	Unable to work		

TIME TAKEN FOR FRACTURE UNION:

FRACTURE TYPE	AVERAGE TIME FOR UNION(WEEKS)	AVERAGE CONSTANT SCORE (mean ± standard deviation)
AO 15 B1	8	90.33 ± 3.91
AO 15 B2	10	89.5 ± 3.16
OVERALL (B1+B2)	8.8	90 ± 3.5

Comparing fracture type and union time we obtained p value 0.047 – statistically significant.

Comparing constant score with fracture type, p value 0.521 – statistically not significant.

FUNCTIONAL EVALUATION USING CONSTANT SCORE:

S. NO.	RESULT	CONSTANT SCORE	NO. OF PATIENTS	PERCENTAGE
1.	EXCELLENT	86-100	18	90%
2.	GOOD	71-85	2	10%
3.	FAIR	56-70	0	0%
4.	POOR	1-55	0	0%

STATISCAL ANALYSIS

The collected data was analysed with SPSS. To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. To find the significant difference between the bivariate samples in Independent groups the Mann-Whitney U test was used. To assess the relationship between the variables Spearman's rank Correlation was used. In both the above statistical tools the probability value .05 is considered as significant level.

NPar Tests

Mann-Whitney Test

Ranks

	SEX	N	Mean Rank	Sum of Ranks
TIME FOR UNION	FEMALE	6	10.17	61.00
	MALE	14	10.64	149.00
	Total	20		

Test Statistics[a]

	TIME FOR UNION
Mann-Whitney U	40.000
Wilcoxon W	61.000
Z	-.169
Asymp. Sig. (2-tailed)	.866
Exact Sig. [2*(1-tailed Sig.)]	.904[b]

a. Grouping Variable: SEX

b. Not corrected for ties.

In this table, sex of the patient was compared with time for union to find any significant difference. The p value obtained was 0.904.

Hence there is no statistical significance between sex of the patient and time for union.

FRACTURE TYPE COMPARED WITH TIME FOR UNION AND CONSTANT SCORE:

Ranks

	AO CLASS	N	Mean Rank	Sum of Ranks
TIME FOR UNION	B1	12	8.33	100.00
	B2	8	13.75	110.00
	Total	20		
CONSTANT SCORE	B1	12	11.25	135.00
	B2	8	9.38	75.00
	Total	20		

Test Statistics[a]

	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2 tailed)	Exact Sig. [2*(1 tailed Sig.)]
TIME FOR UNION	22.000	100.000	-2.053	.040	.047[b]
CONSTANT SCORE	39.000	75.000	-.709	.470	.521[b]

a. Grouping Variable: AO CLASS

b. Not corrected for ties.

When fracture type and time for union are compared, we obtained p value of 0.047 which is statistically significant, where as fracture type and the resultant constant score doesn't show any statistical significance as the p value obtained is 0.521.

NON PARAMETRIC CORRELATIONS :

Correlations

			TIME FOR UNION	CONSTANT SCORE
Spearman's rho	TIME FOR UNION	Correlation Coefficient	1.000	-.015
		Sig. (2-tailed)	.	.949
		N	20	20
	CONSTANT SCORE	Correlation Coefficient	-.015	1.000
		Sig. (2-tailed)	.949	.
		N	20	20

There is no statistical significance when the variables, time for union and constant score are compared as the p value is 0.949, which is statistically not significant.

DISCUSSION

Plate osteosynthesis,(16,17) external fixation,(18) and intramedullary fixation(9,13,19–21) have all been described for surgical treatment of clavicle fractures. Plate osteosynthesis is still considered the standard method for the surgical treatment of clavicle fractures.

The advantage of plate fixation is good reduction with compression and rigid fixation.

However, complications after plate osteosynthesis are fairly common. In a multicenter prospective randomized trial, plate osteosynthesis had better functional outcome than non-operative treatment of displaced clavicle fractures with decreased rate of non-union and symptomatic malunion.(16).

Severe complications occur in 10% of the patients and include deep infection, non-union, implant failure, and fracture after implant removal. Lesser complications include superficial infection, keloid scar, dysesthesia in the region of scar, as well as implant loosening with loss of reduction.(22)

Intramedullary stabilization is an established alternative fixation method.

Intramedullary implants are ideal from the biomechanical point of view as the tension side of clavicle changes with respect to rotation of arm and direction of loading.(7,13).

The other potential benefits of intramedullary nailing include smaller incision, minimal periosteal stripping, and load sharing device properties.(12) Its relative stability allows copious callus formation during the healing process.

The frequent complication encountered is skin irritation from the prominent medial end of the nail and this frequently leads to premature removal of the nail(22).

Usage of tens nail in multifragmentary fracture can lead to telescoping of the nail with shortening of the clavicle. Thus the comminuted fractures were excluded as the nail cannot maintain length of the clavicle in these situations. Smekal et al. hence do not recommend use of intramedullary nail in comminuted fractures with severe shortening.(22)

Duan et al. in a meta-analysis of randomized controlled trials demonstrated similar functional outcome when comparing plating with intramedullary fixation.(1)They, however, showed higher symptomatic hardware-related problems with plating.

Zolowodzki et al. in a systematic review of 2144 cases found non-union rate of 1.6% with intramedullary fixation as compared with 2.5% with plate fixation.(1)

As we discussed the various advantages of the technique,there were certain difficulties which we experienced. Achieving closed reduction was the a difficult task especially in AO B2 fractures and in obese individuals. We attempted various aids like use of percutaneous reduction clamps and drilling a k-wire into the fragment to manipulate.

Inspite of these measures, if still reduction could not be achieved closed, a mini open incision can be made to reduce the fracture . So that the surgical time as well as the radiation exposure for both the patient and surgeon can be reduced.

We do not consider open reduction of the fracture as unsatisfactory as despite its high rate, in our series, we achieved 100% union.

Despite all these, we achieved good functional and cosmetic outcome in diaphyseal midshaft, non-comminuted clavicle fractures with more than 20mm shortening/displacement with intramedullary titanium elastic nail system with no major complications.

In our study there is significant statistical correlation between fracture type and time for union ($P < .047$) although no other variable showed statistical significant.

SUMMARY

At the end of the study, we had all the 20 patients in the follow up group with 14 male and 6 female patients. The mean age was 34.9 years (range 22‑55 years) in the group.

The mean time interval between injury and surgery was 3.55 days (range 1‑6 days). In the group 12 patients had AO class B1 and 8 had AO class B2 fractures.

All the patients achieved clinical and radiological union at a mean of 8.8 weeks (Range, 6-12 weeks). Eleven of the 20 patients had closed nailing while 9 patients (45%) required open reduction of their fracture. The average size of the titanium flexible nail used was 2.5 mm (range, 2 - 3 mm)

The patients were followed up postoperatively and CONSTANT scores were calculated at 6 weeks, 3 months, 6 months. The average constant score was 90 (range 82 – 94).

The nails were removed at an average of 6 month postoperatively, after the fracture had clinically and radiologically healed.

One patient had medial protrusion of the nail with local skin perforation which was subsequently removed early after fracture has united at around 3 months.

There were no major complications in our series with only one case of local skin infection due to medial hardware prominence.

No other complications like scar neuromas, non-unions or perforation of the posterior cortex were reported. And there were no cases of refracture after implant removal.

CONCLUSION

Thus the intramedullary fixation of displaced midshaft clavicle fracture is a safe minimally invasive technique.

From this study, we recommend the use of minimally invasive antegrade titanium elastic nail for fixation of displaced midshaft clavicle fractures in view of :

- faster fracture union,
- earlier rehabilitation
- lesser morbidity,
- easier implant removal and
- fewer complications

although for comminuted fractures plating remains the procedure of choice.

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MASTER CHART

S.No	NAME	AGE	SEX	MODE OF INJURY	LIMB INVOLVED	AO classification	ASSOCIATED INJURIES	DAYS BEFORE SURGERY	FOLLOW UP IN MONTHS	TIME FOR UNION IN WEEK	SHOULDER MOVEMENTS				CONSTANT SCORE	RESULT
											flexion	Abduction	ER	IR		
1.	NALINI	45	F	FOOSH	R	B1		3	11	6	145	150	65	70	85	GOOD
2.	PARTHIBAN	32	M	RTA	L	B1		4	13	6	160	170	75	80	92	EXCELLENT
3.	VENKATESH	24	M	RTA	R	B1		3	10	12	180	170	70	75	94	EXCELLENT
4.	SUGENDHER	26	M	FFH	R	B2		1	9	10	180	180	75	80	92	EXCELLENT
5.	DHAYALAN	39	M	RTA	L	B1		1	10	12	170	175	75	70	94	EXCELLENT
6.	ISMAIL	23	M	RTA	L	B1	I/L Scapula Spine #	2	8	8	165	170	70	70	90	EXCELLENT
7.	SELVAM	52	M	RTA	R	B2		4	12	8	170	175	65	70	86	EXCELLENT
8.	DEVAKI	48	F	FOOSH	L	B1		4	4	8	145	140	65	65	82	GOOD
9.	RADHIKA	23	F	RTA	R	B1		3	9	6	170	170	75	80	94	EXCELLENT
10	SUDAKAR	35	M	RTA	R	B1		5	8	7	170	165	70	70	90	EXCELLENT
11	YOGESH	25	M	RTA	R	B1		3	6	6	165	170	70	70	94	EXCELLENT
12	MOOSA	44	M	FOOSH	R	B2		4	6	12	170	165	65	70	86	EXCELLENT
13	PONNI	35	F	RTA	L	B2		3	9	10	170	180	70	75	90	EXCELLENT
14	BHARANI	28	M	FFH	L	B2	BB Leg #	2	12	10	165	I75	85	80	94	EXCELLENT
15	VIKRAM	46	M	RTA	R	B1		6	10	10	165	160	70	75	87	EXCELLENT
16	DEVI	32	F	RTA	R	B2		3	10	12	170	170	75	75	90	EXCELLENT
17	SOMNATH	22	M	RTA	L	B1		5	12	6	170	165	85	70	92	EXCELLENT
18	KAMALA	55	F	FOOSH	R	B2		6	8	10	155	150	65	75	86	EXCELLENT
19	VETRI	41	M	RTA	L	B1		5	11	9	160	155	75	80	90	EXCELLENT
20	GODWIN	23	M	RTA	R	B2		4	9	8	170	170	85	85	92	EXCELLENT

PROFORMA

Name :

Age / Sex :

IP number :

Address :

Contact Number :

Date of Admission :

Date of Surgery :

Date of Discharge :

Occupation :

Education :

Socioeconomic Status :

Diagnosis :

HISTORY :

1. Mode of injury : Road traffic accident / Fall at home / Fall from height / Assault
2. Presenting complaints :

a. Pain – site / duration

b. Swelling – site / extent

c. Deformity

d. Disturbances in function – movements

e. Other associated injuries – head injury / limb injuries / spine injuries

3. Comorbid illnesses :

Diabetes mellitus		Hypertension		Coronary heart disease	
Renal disorder		Seizures /Neurological disorder		Hepatic disorder	
Dyslipedemia		Endocrine disorder		Tuberculosis	
Bronchial Asthma		Chronic Obstructive lung diseases		Neoplastic disorders	

4. Drug history : Steroids / Disease modifying anti-rheumatoid drugs / Immunosuppresants

PAST HISTORY:

- Any similar injuries
- Previous surgeries or hospitalisations
- Any major illnesses

PERSONAL HISTORY:

TREATMENT HISTORY:

FAMILY HISTORY:

CLINICAL EXAMINATION:

GENERAL EXAMINATION:

- ☞ Appearance : ☞ Built :
- ☞ Pallor : ☞ Icterus :
- ☞ Cyanosis : ☞ Clubbing :
- ☞ Pedal Edema : ☞ Lymphadenopathy :

VITALS:

1. Pulse :

2. BP :
3. Respiratory rate :
4. Temperature :

SYSTEMIC EXAMINATION :

- ☞ Cardiovascular system :
- ☞ Respiratory system :
- ☞ Abdomen :

REGIONAL EXAMINATION

RIGHT / LEFT SHOULDER

OTHER INJURIES

X – RAY FINDINGS :

FINAL DIAGNOSIS:

INITIAL TREATMENT GIVEN:

TIME INTERVAL BETWEEN INJURY AND SURGERY :

PROCEDURE DONE :

MOBILIZATION STARTED ON :

COMPLICATIONS:

POST OP PERIOD :

FIRST WEEK			
SIXTH WEEK			
THIRD MONTH			
SIXTH MONTH			

FOLLOW UP PERIOD :

CONSTANT SCORE :

FUNCTIONAL OUTCOME :

CONSENT FORM

நோயாளி ஒப்புதல் படிவம்

Bµð´a] °ß Ã Áµß:
PÊz x £mø h G¼ß¦ ¬ÔÃ ØS øhmhßÜ¯®P® o ôEßÖzx® AÖøÁ]Qøø \ °ß £¯ßPø Í ÁÖ²® B´Á¶µøP

ஆராய்ச்சி மையம்அரசு கீழ்பாக்கம் மருத்துவக் கல்லூரி மருத்துவமனை

நோயாளியின் பெயர் நோயாளியின் வயது

பதிவு எண்

நோயாளி கீழ்கண்டவற்றுள் கட்டங்களை செய்யவும்

- மேற்குறிப்பிட்டுள்ள ஆராய்ச்சியின் நோக்கத்தையும் பயனையும் முழுவதுமாக புரிந்துகொண்டேன் மேலும் எனது அனைத்து சந்தேகங்களையும் கேட்டு அதற்கான விளக்கங்களையும் தெளிவுபடுத்திக் கொண்டேன ☐
- மேலும் இந்த ஆராய்ச்சிக்கு எனது சொந்த விருப்பத்தின் பேரில் பங்கேற்கிறேன் என்றும் மேலும் எந்த நேரத்திலும் எவ்வித முன்னறிவிப்புமின்றி இந்த ஆராய்ச்சியிலிருந்து விலக முழுமையான உரிமை உள்ளதையும் இதற்கு எவ்வித சட்ட பிணைப்பும் இல்லை என்பதையும் அறிவேன் ☐
- ஆராய்ச்சியாளரோ ஆராய்ச்சி உதவியாளரோ ஆராய்ச்சி உபயத்தாரோ ஆராய்ச்சி பேராசிரியரோ ஒழுங்குநெறி செயற்குழு உறுப்பினர்களோ எப்போது வேண்டுமானாலும் எனது அனுமதியின்றி எனது உள்நோயாளி பதிவுகளை இந்த ஆராய்ச்சிக்காகவோ அல்லது எதிர்கால பிற ஆராய்ச்சிகளுக்காகவோ பயன்படுத்திக்கொள்ளலாம் என்றும்மேலும் இந்த நிபந்தனை நான் இவ்வாரய்ச்சியிலிருந்து விலகினாலும் தகும் என்றும் ஒப்புக்கொள்கிறேன் ஆயினும் எனது அடையாளம் சம்பந்தப்பட்ட எந்த பதிவுகளும்சட்டபூர்வமான தேவைகள் தவிரவெளியிடப்படமாட்டாது என்ற உறுதிமொழியின் பெயரில் இந்த ஆராய்ச்சியிலிருந்து கிடைக்கப்பெறும் முடிவுகளை வெளியிட மறுப்பு தெறிவிக்கமாட்டேன் என்று உறுதியளிக்கின்றேன் ☐
- இந்த ஆராய்ச்சிக்கு நான் முழுமனதுடன் சம்மதிக்கின்றேன் என்றும் மேலும் ஆராய்ச்சிக் குழுவினர் எனக்கு அளிக்கும் அறிவுரைகளை தவறாது பின்பற்றுவேன் என்றும் இந்த ஆராய்ச்சி காலம் முழுவதும் எனது உடல் நிலையில் ஏதேனும் மாற்றமோ அல்லது எதிர்பாராத பாதகமான விளைவோ எற்படுமாயின் உடனடியாக ஆராய்ச்சி குழுவினரை அணுகுவேன் என்றும் உறுதியளிக்கின்றேன் ☐
- இந்த ஆராய்ச்சிக்குத் தேவைப்படும் அனைத்து மருத்துவப் பரிசோதனைகளுக்கும் ஒத்துழைப்பு தருவேன் என்று உறுதியளிக்கின்றேன் ☐
- இந்த ஆராய்ச்சிக்கு யாருடைய வற்புருத்தலுமின்றி எனது சொந்த விருப்பத்தின் பேரிலும் சுயஅறிவுடனும் முழுமனதுடனும் சம்மத்திக்கின்றேன் என்று இதன் மூலம் ஒப்புக்கொள்கிறேன் ☐

நோயாளியின் கையொப்பம்பெருவிரல் கைரேகை ஆராய்ச்சியாளரின் கையொப்பம்

இடம் தேதி